Decision Memo for Electrostimulation for Wounds (CAG-00068R)

Decision Summary

CMS determines that the results from electromagnetic stimulation of chronic, nonhealing wounds are similar to the results from electrical stimulation of similar wounds and that both are reasonable and necessary for the treatment of chronic, nonhealing wounds. Therefore, we will modify our current national coverage determination to add coverage for electromagnetic stimulation.

CMS determines that the current evidence is not adequate to conclude that electromagnetic stimulation improves outcomes in settings outside those covered for electrical stimulation and will, therefore, limit coverage of electromagnetic stimulation to those settings and conditions for which electrical stimulation is covered.

Therefore, it is our intention to modify CIM 35-102 to allow for coverage for the use of electrical and electromagnetic stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical and electromagnetic stimulation for the treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence.

Electrical stimulation and electromagnetic therapy for the treatment of wounds will not be covered as an initial treatment modality. The use of electrical and electromagnetic stimulation will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Specific wound care based on type of wound includes frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers; and the use of a compression system for patients with venous ulcers. Wounds must be evaluated at least every 30 days during administration of electrical and electromagnetic stimulation therapy. Continued treatment with electrical and electromagnetic stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Electrical and electromagnetic stimulation should be discontinued when the wound demonstrates a 100% epithelialzed wound bed. Electrical and electromagnetic stimulation for wound healing are not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction, program memorandum, CMS ruling or Federal Register Notice, giving specific directions to our claims processing contractors. That issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

To: Administrative File: CAG# 00032R Electromagnetic Therapy for the Treatment of Chronic Wounds

From:

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group

Jesse Polansky, M.D., M.P.H.
Division Director, Division of Items and Devices

Lorrie Ballantine
Lead Analyst, Division of Items and Devices

Joseph Chin, M.D., M.S.
Medical Officer, Division of Medical and Surgical Services

Re: Coverage Decision Memorandum for Reconsideration of Electrostimulation (Electrical Stimulation) for the Treatment of Chronic Wounds

Date: December 17, 2003

I. Decision

CMS determines that the results from electromagnetic stimulation of chronic, nonhealing wounds are similar to the results from electrical stimulation of similar wounds and that both are reasonable and necessary for the treatment of chronic, nonhealing wounds. Therefore, we will modify our current national coverage determination to add coverage for electromagnetic stimulation.

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Electrical stimulation and electromagnetic therapy for the treatment of wounds will not be covered as an initial treatment modality. The use of electrical and electromagnetic stimulation will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Specific wound care based on type of wound includes frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers; and the use of a compression system for patients with venous ulcers. Wounds must be evaluated at least every 30 days during administration of electrical and electromagnetic stimulation therapy. Continued treatment with electrical and electromagnetic stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Electrical and electromagnetic stimulation should be discontinued when the wound demonstrates a 100% epithelialzed wound bed. Electrical and electromagnetic stimulation for wound healing are not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary.

II. Clinical Background

The normal wound healing process involves inflammatory, proliferative, and remodeling phases. When the healing process fails to progress properly and the wound persists for longer than one month, it may be described as a chronic wound. The types of chronic wounds most frequently addressed in studies of electromagnetic therapy for wound healing are (1) pressure ulcers; (2) venous ulcers; (3) arterial ulcers; and (4) diabetic ulcers.

Pressure ulcers, also known as decubitus ulcers, bedsores or pressure sores, are areas of localized skin/tissue damage caused by unrelieved pressure. This pressure squeezes the skin's blood vessels causing hypoxia. If the pressure is prolonged it results in tissue necrosis. Pressure ulcers are most common over bony prominences, such as the sacrum, heels, hips and elbows. Pressure ulcers are generally classified by stage (See Table 1). Stage I pressure ulcers present as non-blanching erythema with intact skin. Stage II ulcers are a partial thickness loss involving the epidermis or dermis. Stage III ulcers are full thickness and extend down to, but not through, the underlying fascia. Stage IV ulcers involve tissue below the fascia, exposing muscle and even bone.

Table 1: Staging of pressure ulcers

Stage I	Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area of the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue or purple hues.
Stage II	Partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater.
Stage III	Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
Stage IV	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Prevention of pressure ulcers involves frequent repositioning of the patient, keeping the skin dry and, in some cases, using various support surfaces that keep a person's weight evenly distributed. Once these wounds develop, standard wound care includes frequent turning to relieve pressure, proper nutrition and good hygiene. The underlying immobility and difficulty relieving surface pressure points often makes treating these wounds a challenge.

Venous ulcers usually occur in the lower extremities. They result from venous obstruction or valvular incompetence. The subsequent venous hypertension then affects the vascular supply to surrounding tissue, resulting in tissue hypoxia and ulcer formation. Because the underlying pathophysiology is venous insufficiency, the treatment of venous ulcers should ultimately be directed on two fronts–correction of the underlying venous incompetence and wound care. Moist dressings combined with compressive stockings are usually effective in treating these ulcers, although the time to heal may be prolonged in some patients.

Diabetic ulcers are thought to develop from a combination of both small and large vessel disease, which affects tissue perfusion, and peripheral neuropathy, which leads to a loss of protective sensation. Injuries in these patients are often slow to heal and might go unnoticed. Foot ulcers are a major health problem for diabetics. It is estimated that up to 15% of diabetics will develop a foot ulcer at some time in their life, and approximately 70% of such patients develop recurrent ulcers.[1] Diabetic foot ulcers precede approximately 85% of lower limb amputations.[2] Educating diabetics about routine foot care and self-examination can help to prevent foot ulcers. Moist dressings, debridement and off-loading are the mainstays of treatment.

Arterial ulcers result from inadequate blood flow to the site of a lesion to which blood flow is compromised. The ulcer may be very deep and usually appears black, necrotic, and has no granulation tissue. The surrounding tissue typically shows signs of arterial insufficiency, such as loss of nail growth or atrophic skin. These ulcers usually form between the toes, or on the ankle where the bone protrudes, or on the back of the foot. These ulcers may be very painful and are usually associated with diseases such as arteriosclerosis, systemic lupus erythematosis, or thromboangiitis obliterans. Treatment of the vascular impairment is an important component of good wound care.

Conventional or standard therapy for chronic wounds involves local wound care as well as systemic measures. Standard care considerations to promote wound healing include debridement or removal of necrotic tissue, wound cleansing, and dressings that promote a moist wound environment. Systemic treatments include the use of antibiotics to control infection and optimizing nutritional status. There are other conventional therapeutic modalities that may apply to certain subgroups of patients depending on their type of wound. Specific conventional therapies for venous ulcers include the use of compression devices aimed at decreasing venous stasis. Patients that have pressure ulcers require frequent repositioning to redistribute the pressure that is causing the ulcers. Other standard therapies include off-loading and good glucose control for diabetic foot ulcers and establishment of adequate circulation for arterial ulcers.

Electromagnetic therapy is a form of treatment that involves the production of induced current from the application of electromagnetic fields rather than the application of electrical current directly from electrodes on the skin surface.[3] It is used as an adjunct to standard therapy and is not a substitute for standard wound therapy, such as wound cleansing, dressing changes, debridement, regular examination by health care professionals and treatment of infections identified during examinations.

Electromagnetic therapy uses a pulsed magnetic field to induce an electric current. The same type of device can be used with a continuous magnetic field; in this mode, called diathermy, the currents produce significant heating of the tissue. When used in the pulsed mode, the currents are produced for only a short amount of time, so the heating effects, at most, are small.[4] Electromagnetic fields vary in frequency and strength. The highest frequency radiation, gamma and x-rays, have been used for diagnostic imaging. Unfortunately, they may also damage human tissue because of their ionizing properties. In the middle of the electromagnetic spectrum is ultraviolet and infrared light. At the low end of the frequency range are microwaves and radiowaves, which are used by at least some electromagnetic therapy devices. The Federal Communication Commission (FCC) assigned medical shortwave a carrier frequency of 27.12 MHz to avoid interference with public communication. At a frequency of 27.12 MHz, and a pulse duration of 65 microseconds, as in the case of Diapulse, a pulse would contain 1762.8 oscillations per second. It has been suggested that these devices may alter or augment pre-existing endogenous electrical fields and may trigger specific, measurable cellular responses such as DNA synthesis, transcription and protein synthesis. However the physiological mechanisms underlying the purported clinical effects of electromagnetic therapy are not clear and remain theoretical.[5]

III. History of Medicare Coverage

Medicare coverage for electrical stimulation for wound healing has been historically left to carrier discretion. In 1981 CMS issued a national noncoverage determination, which barred coverage of low intensity direct current electrical stimulation used for the treatment of pressure sores (Medicare Medicaid Guide Sep. 20, 1981). Carriers' had the discretion to cover other forms of electrical stimulation devices. In August 1995, CMS ordered a technology assessment of electrical stimulation for wound healing. Emergency Care Research Institute (ECRI), a technology assessment firm, was awarded the contract. This report was completed in February 1996.

In 1997, CMS issued a national noncoverage policy for electrical stimulation for the treatment of wounds. However, CMS did not implement this policy because the federal district court in Massachusetts remanded the national coverage determination back to the Secretary and coverage of electrical stimulation for wounds remained at carrier discretion.

On July 23, 2002, CMS published a decision memorandum announcing our intention to issue a positive national coverage determination for the use of electrical stimulation for the treatment of wounds. As part of that determination we announced that Medicare would not cover any form of electromagnetic therapy for the treatment of chronic wounds.

The Diapulse Corporation of America, Inc., the manufacturer of a non-thermal, pulsed, high frequency, high peak power electromagnetic device called Diapulse®, submitted a request for reconsideration of the electrical stimulation policy. Diapulse asserts that (1) electromagnetic therapy is the same as electrical stimulation and, therefore, should be covered under the current national policy; and (2) clinical studies using Diapulse® support national coverage whether or not electromagnetic therapy is the same as electrical stimulation. We provide a fuller description of the company's assertions below.

Benefit Category Determination:

1861(s)(1) Physician's Service
1861(s)(2)(A) Services and Supplies furnished incident to a physician's service
1861(p) Outpatient Physical Therapy Services

IV. Timeline of Recent Events

October 18, 2002	CMS accepts Diapulse Corporation of America's formal request for reconsideration.
November 15, 2002	CMS met with representatives from Diapulse, who demonstrated the machine.
December 23, 2002	CMS extended the due date to February 21, 2003 to allow for the review of new material submitted by Diapulse Corporation of America.
January 23, 2003	CMS met with representatives from Diapulse, who demonstrated the machine and discussed their belief that Diapulse is a type of electrical stimulation, as stated in the ECRI report.
November 3, 2003	Representatives from Diapulse met with senior staff from the Office of Clinical Standards and Quality and demonstrated the machine.

V. Food and Drug Administration (FDA) Status

The FDA has cleared Electromagnetic Energy devices under the 510(k) clearance process. A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed predicate device. The FDA considered Diapulse® (one such electromagnetic device) a Pre-amendment Class III device that was formally “grandfathered” on March 27, 1987. Diapulse Corporation did provide the FDA animal and human studies with their application. The classification device for products in this category is a Diathermy device, for use other than applying deep heat.

In a letter dated March 1991 from the FDA to the Diapulse Corporation, the FDA stated that Diapulse® could only be marketed as adjunctive therapy in the palliative treatment of postoperative edema and pain in superficial soft tissue. The FDA has not cleared or approved the use of any electrical stimulation or electromagnetic device for the treatment (healing) of chronic wounds.

The FDA also considers the use of these devices for the treatment (healing) of wounds to be significantly different than the use of these devices for the indications currently covered under a 510(k) clearance. When used to treat wounds, these devices are considered by the FDA to be Class III devices, which require the manufacturer to go through the Premarket Approval (PMA) process.[6] Therefore, manufacturers would have to submit valid scientific evidence to show that their products provide reasonable assurance of safety and effectiveness for the treatment of wounds before the FDA would approve a PMA application. As of this time, the law prohibits manufacturers from marketing the use of electromagnetic devices for wound healing. Lack of approval for this particular indication, however, does not preclude physicians and other health care providers from providing this therapy for an unapproved use. In addition, lack of FDA approval or clearance for a specific non-labeled indication, when there are other labeled indications, is not an automatic disqualification for Medicare coverage.

In addition, CMS assesses relevant health outcomes, above and beyond the safety and effectiveness regulatory mandate of the FDA. Although a device must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage, except for a category B device under an investigational device exemption (IDE) clinical trial (60 FR 48417, September 19, 1995), FDA approval/clearance alone does not entitle that device to coverage. The device must fall under a Medicare benefit category and be determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be covered by CMS. CMS has the authority to conduct a separate assessment of a device’s appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries (see e.g., 60 FR 48417, 48420 (September 19, 1995). Under a premarket approval application (PMA) review, the FDA determines whether or not there is reasonable assurance of safety and effectiveness for the device’s intended use that is stated in its proposed labeling. Medicare NCDs consider the medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. CMS determines whether or not the intervention improves net health outcomes in the Medicare population at least as well as established treatments. Thus, FDA PMA approval by itself is not sufficient for making a determination concerning Medicare coverage.

As we similarly stated in 66 FR 58788, 58797 (November 23, 2001) with regard to FDA 510(k) clearance, "[t]he criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug, and Cosmetic Act is significantly different from the scientific evidence we consider in making "reasonable and necessary" determinations under Medicare. FDA does not necessarily require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare NCDs consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage."

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of reasonable and necessary. The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical questions relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention’s risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias);
- Co-interventions or provision of care apart from the intervention under evaluation (confounding);
- Differential assessment of outcome (detection bias);
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. The goal of our determination process is to assess net health outcomes, and we are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

An intervention is not reasonable and necessary if its risks outweigh its benefits. For all determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

VII. Evidence

A. Introduction

When considering evidence on treatments for chronic wounds, the most important health outcome is complete wound healing. Rate of wound healing has also been studied but may be considered an intermediate outcome. Regardless of the specific outcome, studies on wound healing are prone to bias due to the many potential confounding variables. For example, the size and chronicity of a particular wound greatly influences the rate of healing and ultimately complete wound-healing depending on length of the follow up time. Therefore, appropriately designed studies and adequate multivariate analyses to adjust for confounders are essential to fully evaluate wound-healing modalities.

To specifically evaluate electromagnetic therapy, we searched Medline from 1989 to the present using keywords “electromagnetic” or “Diapulse” and “wounds” or “ulcers.” Studies on cellular responses, tissue cultures and animals were excluded for the purpose of assessing whether or not these devices are reasonable and necessary. Several studies were found and are summarized below. In addition, the Diapulse Corporation submitted 35 citations. Of these, 6 dealt directly with chronic wounds or ulcers (5 were already included; 1 prior to 1989 was added to our review). The other articles did not address chronic wounds directly or involved cellular and tissue experiments. In addition, studies prior to 1970 were not considered since the design, conduct and analyses used in these studies are not comparable to more current research protocols.

B. Discussion of Evidence Reviewed

The development of an assessment in support of Medicare coverage decisions is based on the same general question for almost all requests: “Is the evidence adequate to conclude that the application of the technology under study will improve final health outcomes for Medicare patients?” The formulation of specific questions for the assessment recognizes that the effect of an intervention can depend substantially on how it is delivered, to whom it is applied, the alternatives with which it is being compared, and the setting in which it is delivered.

1. Questions: In order to appraise the net health outcomes of electromagnetic stimulation for treating of chronic, nonhealing wounds in comparison with standard wound therapy and identify any relevant patient and facility selection criteria, CMS sought to address the following question:

Is the evidence adequate to conclude that electromagnetic therapy improves net health outcomes for Medicare beneficiaries with chronic wounds?

2. External technology assessments

In 2001, Cullum et al. published a technology assessment that was commissioned by the United Kingdom’s National Health Service (NHS) Research and Development Health Technology Assessment Programme. The technology assessment reported the following: “Only three small trials with a total of 92 patients were identified. These trials provided no evidence of a benefit of electromagnetic therapy for venous leg ulcers.” [7] In 2002, Flemming and Cullum published an amendment to their 2001 technology assessment for the Cochrane Review. The 2002 review was not considered as part of our evaluation of electrical stimulation described in our July 23, 2002 decision memorandum. The Cochrane Review stated: “Electromagnetic therapy is distinct from most other forms of electrotherapy in that it is a field effect and not a direct electrical effect.”[8] They prepared two systematic evidence reviews on electromagnetic therapy for the treatment of venous leg ulcers and pressure ulcers to assess effectiveness. The authors reported:

- “There is currently no reliable evidence of benefit of electromagnetic therapy in the healing of venous leg ulcers.”

- "The results suggest no evidence of a benefit in using electromagnetic therapy to treat pressure sores. However the possibility of a benefit or harmful effect cannot be ruled out due to the fact there were only two trials with methodological limitations and small number of patients."

3. Summary of Evidence

Diapulse Corporation of America's Request for Reconsideration

In our July 23, 2002 decision memorandum on electrical stimulation for the treatment of chronic wounds,[9] we announced our intent to issue a national coverage determination for electrical stimulation devices for the treatment of chronic wounds and a national noncoverage determination for electromagnetic therapy devices, because the evidence as a whole was not adequate to conclude that electromagnetic therapy devices for the treatment (healing) of chronic wounds are reasonable and necessary. As we stated in that memorandum, "[e]lectrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound" whereas "[e]lectromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields rather than direct current."

In the opinion of the Diapulse Corporation, CMS erred in concluding that electrical stimulation and electromagnetic therapy should be treated differently and that the evidence is adequate to conclude that Diapulse® is reasonable and necessary, including when used unsupervised in the home setting. The company made several assertions in support of its request for reconsideration, as follows:

1) The Agency for Health Care Policy and Research's (AHCPR)[10] 1994 Guideline on Treatment of Pressure Ulcers stated the following: "Electrical Stimulation. The use of an electrical current to transfer energy to a wound. The type of electricity that is transferred is controlled by the electrical source." The company states that "since Diapulse® transfers electrical energy to a wound, the definition clearly encompasses Diapulse®." The Guideline advises clinicians to "consider a course of electrotherapy for Stage III and IV pressure ulcers that have proved unresponsive to conventional therapy."
2) The ECRI report considered electrical stimulation and electromagnetic therapy collectively.
3) The ECRI report stated that "[t]here is evidence that Pulsed Electromagnetic Energy (PEE) stimulation improves the normalized healing rate for stage II decubitus ulcers."
4) CMS primarily used the ECRI report to determine coverage for electrical stimulation.
5) "ECRI should have provided CMS with the original published peer review medical journal" article of the Salzberg et al. study.
6) CMS's search for additional studies following the 1996 ECRI report found studies whose results "did not demonstrate under the CMS definition of Electrical Stimulation anything more positive than previous references used by CMS to deny coverage."
7) "There are 25 Medline articles, and many on wounds that were randomized double-blind controlled studies published in peer review journals, which clearly demonstrate the value of non-thermal pulsed electromagnetic energy in accelerating wound healing." CMS erred by not reviewing all the relevant studies. When CMS conducted a Medline search they should have included Diapulse® in key words, and not limit the search in any manner.
8) CMS should not have relied on the [National Health Service's] HTA Technology Assessment conducted by the Cochrane Review, because the review findings were not accurate.
9) "In Judge O'Toole's MEMORANDUM AND ORDER November 18, 1977 [Aitken v. Shalala], the Court did not limit electrical stimulation to only four categories set up by CMS, Diapulse® was not excluded."

10) CMS's 2002 decision memorandum stated "[t]here was insufficient evidence to determine the best type of device and most effective form of electrical stimulation for the treatment of chronic wounds or ulcers. There appears to be no standard type, waveform, or frequency of electrical stimulation….Therefore, CMS cannot determine if one type of electrical stimulation is more or less clinically effective than another type."
11) According to the company, "CMS decided to provide electrical stimulation coverage for the treatment of chronic wounds and erred when they excluded the only approved wound treatment, Diapulse®."
12) The Medicare Coverage Advisory Committee (MCAC) when it met in 2000 to evaluate the adequacy of the evidence for electrical stimulation as a treatment of chronic wounds concluded that they remained uncertain about whether there are differences in the technologies.
13) CMS erred by concluding, "electrical stimulation for wound healing is not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary." According to the company, "CMS did not review information that Diapulse® has been proven to be medically reasonable and necessary for use by patients in the home."
14) CMS excluded Diapulse® from consideration as electrical stimulation without providing an explanation or support. "However, under the proper definition, all evidence and rationales supportive of the CMS's coverage decision apply equally to Diapulse®."

Controlled Trials

In 1990, Ieran et al. reported the results of a double blind, randomized controlled trial to evaluate the effect of electromagnetic therapy on venous ulcers. Forty-four patients who had skin lesions for at least 3 months were randomized to active treatment (n=22) or control group (n=22). Active treatment involved single pulsed electrical current generating a magnetic field of 2.8mT at a frequency of 75 Hz, with an impulse width of 1.3 ms. Compression, which is part of standard wound care for venous ulcers and routinely used in the investigators' clinic, was "omitted to be able to evaluate the effect of electromagnetic stimulation alone." Patients were instructed to use the electromagnetic devices for 3-4 hours per day at home. The study team evaluated patients biweekly. Of the patients randomized, 3 patients in the control group and 4 patients in the active group were excluded from the analyses (5 for noncompliance, 1 for allergic drug reaction, 1 after receiving a diagnosis of rheumatoid arthritis). In addition, 7 ulcers (37%) in the control group were larger than 15 cm^2 compared to 4 (22%) in the experimental group. At 90 days, 6 patients (31.5%) were healed in the control group and 12 (66.6%) in the experimental group ($p<0.02$). [11] In this study, the sample size was small. Multivariate analyses to control for confounder variables, such as baseline ulcer size and other prognostic factors, were not reported. Unsupervised wound therapy was conducted at home.

In 1991, Todd et al. reported the results of a double blind, controlled study on the treatment of chronic varicose (venous) ulcers with electromagnetic therapy. Nineteen patients were assigned to standard therapy with either active or inactive electromagnetic therapy (magnetoplus 1500 generator). A clinician performed active therapy. The treatment involved pulsed electromagnetic fields (PEMF) with a frequency of 5 Hz for 15 minutes twice a week for 5 weeks. The investigators found no statistically relevant differences between groups in healing rates of ulcers.[12] In this study, the sample size was small. Patients were not randomly assigned so selection bias may have been an issue. Supervised wound therapy was provided in the hospital setting.

In 1992, Stiller et al. reported the results of a double blind, randomized controlled trial on the use of pulsed electromagnetic limb ulcer therapy (PELUT) to enhance healing of venous ulcers. Thirty-one patients with an ulcer for at least 2 weeks were randomized to active treatment or inactive placebo groups. Active treatment consisted of low energy pulsed electromagnetic field stimulation using a portable unit for 3 hours each day at home for 8 weeks or until the ulcer healed. Patients were evaluated every 4 weeks up to a maximum of 12 weeks. Of the 31 patients, 4 (1 active, 3 placebo) did not complete the study. At week 8, the active treatment group had a 47.1% (extrapolated) decrease in wound surface area compared to a 42.3% (extrapolated) increase in the placebo group (one sided $p<0.0002$). [13] The number of wounds that completely healed, the critical outcome measure discussed above, was not reported. In this study, the sample size was small. One-sided statistical tests, which are generally more liberal, were used, but two-sided tests would be more appropriate for the evaluation of changes in wound size, because wound sizes can increase or decrease. Extrapolated or last observed wound area measurements were carried forward to week 8 for patients who did not complete the trial. Unsupervised therapy was conducted at home.

In 1995, Salzberg et al. reported the results of a double blind, randomized controlled trial on the effects of electromagnetic therapy (Diapulse®) on healing of pressure ulcers in hospitalized patients with spinal cord injuries. Twenty hospitalized patients with stage II pressure ulcers and 10 patients with stage III pressure ulcers were separately randomized to active treatment or inactive placebo treatment, although the method of randomization was not provided. Of the stage II ulcers, 10 patients received active therapy with pulsed electromagnetic energy at 27.12 MHz radio frequency, 80 to 600 pulses per second, pulse width (duration) of 65 microseconds for 30 minutes twice daily for 12 weeks or until the ulcer healed. Of these 20 patients, 19 patients completed the trial. The active group had a median time to healing of 13 days compared to 31.5 days for the placebo treatment group ($p=0.002$).[14] However, of the 5 pressure ulcers greater than 60 cm^2, only 1 was in the active group. For healing rates, baseline wound size is an important prognostic factor. Of the 10 patients with stage III ulcers, no statistically significant differences were reported. In this study, the sample size was small. All stage II ulcers in both groups healed by the week 12 endpoint so there was no difference in the critical outcome of complete wound healing. Supervised therapy was provided in the hospital setting.

In 1996 Kenkre et al. reported the results of a double blind, randomized controlled trial of electromagnetic therapy for venous leg ulcers. Nineteen patients with venous ulcers for at least 4 weeks were randomly assigned to active therapy with electromagnetic therapy (Elmedistraal) with frequency of 600 Hz (n=5) or 800 Hz (n=5; 600 Hz on days 1-5 then 800 Hz on days 6-30) for 30 minutes on weekdays in a clinic for 30 days or placebo treatment (n=9). This was followed by a 4-week observation period and a final assessment on day 50. At baseline, the mean ulcer area was 2 times larger in the placebo group compared to the 600 Hz active group and the mean duration of ulceration was more than 4 times longer in the placebo group compared to the 600 Hz group (963 weeks in the control group, 230 weeks in the 600 Hz group, and 418 weeks in the 800 Hz group). At day 30, 1 patient had healed in the placebo group. At day 50, 2 (22%) patients were healed in the placebo group, 1 (20%) in the 600 Hz treatment group; and 1 (20%) in the 800 Hz group. The 800 Hz group had significantly larger reductions in ulcer area compared to the placebo group. The 600 Hz group had less reduction in ulcer area compared to the placebo group.[15] In this study, the sample size was small for 3 test groups. Univariate analyses were reported. Multivariate analyses to control for confounding variables, such as ulcer size and chronicity, at baseline were not reported. The numbers of patients completely healed were similar in all 3-test groups at the day 50 endpoint. Supervised therapy was provided in a clinic.

In 1978, Duma-Drzewinska and Buczynski reported the results of a case series of 27 patients in a rehabilitation unit with bedsores who were treated with electromagnetic therapy (Diapulse ®) at 600 pulses over the sores for 20 minutes and at 400 impulses over the kidney and liver once a day, the rationale for which was not provided. The investigators found that superficial bedsores healed better than those with deep necrosis based on the percent completely healed.[16] In this study, the sample size was small. There was no control group. No statistical tests were performed.

In 1991, Itoh and colleagues reported the results of a case series of 22 hospitalized patients with stage II and III pressure ulcers that had not healed after 3 to 168 weeks of treatment with conventional therapy. Patients were treated with electromagnetic therapy (Diapulse ®) at 27.12 MHz for 30 minutes two times a day. All patients were healed by 22 weeks of conventional treatment and electromagnetic therapy. Eleven (50%) of the patients had small ulcers ($\leq$ 1.00 cm^2).[17] In this study, the sample size was small. There was no control group. Since the patients were hospitalized, the results may not be generalizable to other settings.

In 1993, Comorosan and colleagues reported the results of a case control study on the use of electromagnetic therapy (Diapulse®) for the treatment of pressure ulcers. Thirty hospitalized, terminally ill patients were studied. Twenty patients were selected to receive electromagnetic therapy at 600 Hz for 30 minutes twice a day for up to 8 weeks. Five received conventional therapy of peroxide cleansing, talcum powder, methylene blue and tetracycline ointments. Five received conventional therapy and placebo treatment. All 20 patients in the active treatment group showed very good to excellent results based on a subjective rating of the extent of healing. No patients in either control group showed very good to excellent results (75% or better healing). In this study, the sample size was small. Duration of treatments varied. No statistical tests were performed. The selection and matching of cases and controls was also not.

In 1995, Tung et al. reported the results of a case series on the use of electromagnetic therapy (Diapulse ®) for the treatment of decubitus ulcers in hospitalized patients. Four hospitalized patients with foot or heel ulcers were treated with "meticulous debridements, appropriate antibiotic intervention, adequate nursing care, proper nutrition, and stimulation of tissues with Diapulse® therapy."[18] All ulcers were healed by 43 weeks of treatment. In this case series, the sample size was small. There was no control group. The duration and frequency of electromagnetic therapy stimulation were not reported.

4. MCAC: This issue was not referred to MCAC

5. Evidence-based guidelines

In 1994 the Agency for Health Care Policy and Research issued a Clinical Practice Guideline for the Treatment of Pressure Ulcers. In this review they stated that clinicians could consider a course of treatment with electrotherapy for Stage III and Stage IV pressure ulcers for ulcers that have proved unresponsive to conventional therapy. (Strength of evidence = B) This recommendation was based on 4 studies, none of which used electromagnetic therapy for the treatment of pressure ulcers.

6. Professional Society Position Statements

We contacted numerous health professional organizations, such as the National Pressure Ulcer Advisory Panel and the American Physical Therapy Association, to see if they had any public statements or opinions on the use of electromagnetic therapy for wounds. No health professional organization has published guidelines or consensus statements addressing electrical stimulation or electromagnetic therapy for wounds.

7. Expert Opinion

As part of this reconsideration, we spoke to experts, some of whom were recommended by the Diapulse Corporation, some were experts in wound care and others were experts in bioengineering. The experts disagreed as to whether or not electromagnetic therapy and electrical stimulation were the same and had the same clinical effect on chronic wounds. The two individuals who thought the devices were the same (recommended by the Diapulse Corporation) contended that both types of devices cause electrical current to flow in/through the affected body part. Those experts who disagreed thought that there were important differences in the amount of current delivered to the wound, the frequency of the pulse and the direction of its flow, which could influence the potential health benefit of the therapy.

8. Public Comments

We received 11 letters from beneficiaries, 2 letters from nurses and 2 letters from physicians in support of the use of electromagnetic therapy for the treatment of swelling, pain and wounds. One letter from a wound care device manufacturer stated that “there is no compelling evidence to demonstrate that Diapulse® is an effective means for generating a physiologically significant electrical field on the surface of the body or for healing wounds through this mechanism.”

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act, §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

In our evaluation, we reviewed 5 controlled trials and 4 uncontrolled studies to evaluate whether or not there was adequate evidence that electromagnetic therapy improved net health outcomes in the treatment of chronic wounds. The 4 uncontrolled studies were supportive of electromagnetic therapy. Of the 5 controlled trials, 4 reported results that supported the benefits of electromagnetic therapy on chronic wounds. Of these, 3 (Ieran, Saltzberg, Kenkre) evaluated the critical outcome of complete wound healing.

Three controlled studies (Todd, Saltzberg, Kenkre) were conducted in a supervised setting such as a hospital or clinic. Two controlled studies (Ieran, Stiller) evaluated electromagnetic therapy provided by the patient in the home. Of these, only 1 study (Ieran) reported improvements in the key outcome of complete wound healing from electromagnetic therapy provided in the home setting. This study, however, contained design and methodological flaws such as a small sample size and a high rate of patient exclusions (14% in the control group and 18% in the therapy group). A high exclusion rate may have introduced selection bias. In addition, multivariate analyses to adjust for differences in baseline ulcer sizes between groups were not reported. Seven ulcers (37%) in the control group were larger than 15 cm^2 compared to 4 (22%) in the experimental group, creating incomparable groups at the beginning. As noted earlier, baseline ulcer size is important since larger ulcers tend to heal slower in general than smaller ulcers. Analytic adjustments for baseline ulcer size should have been performed and reported. The study reported by Stiller also evaluated therapy at home but did not evaluate the critical outcome of complete wound healing. It likewise had design, methodological and analytic flaws, such as small sample size, a high dropout rate in the placebo group, use of extrapolated results which assumes a constant healing rate, and use of one-sided statistical tests rather than the more appropriate two-sided tests for wound healing. Thus, it appears that the evidence is more supportive of electromagnetic therapy in a supervised setting and not supportive of electromagnetic therapy provided supervised in the home. This is consistent with traditional electrical stimulation, which is provided by properly trained health professionals in a supervised setting, such as a hospital or clinic.

Although the specific mechanisms of action have not been fully elucidated, both electrical stimulation through electrodes placed on the skin and electromagnetic therapy generate an electrical charge through the wound. If the electrical current through the wound is a primary factor for accelerated healing, then electromagnetic therapy would be a treatment that is physiologically equivalent to electrical stimulation using electrodes applied directly to the skin. In this sense, electromagnetic therapy may serve as an alternative modality to apply electrical current to the wounds by trained health care professionals, as is the case with electrical stimulation using electrodes. Other components of wound healing such as regular wound cleansing, dressing changes, regular examination and treatment of infections by appropriately trained medical professional are also essential and inseparable from electrical therapies and must be continued for maximum healing to be achieved. It is likely that such scrupulous wound care would not be provided to patients treating their own wounds at home, as they may go for lengthy periods without the assessment of a clinical expert in the care of difficult, chronic wounds.

In the prior decision memorandum on electrostimulation for wounds, electromagnetic therapy was considered apart from traditional electrical stimulation through electrodes, largely due to the differing methods of applying therapy. As mentioned earlier, if the electrical current plays a primary role in improved healing, then electromagnetic therapy may be consider similar to electrical stimulation via electrodes. In the prior decision, the evidence on electromagnetic therapy was not completely evaluated since the decision was focused on electrical stimulation, defined as the application of electrical current through electrodes applied directly to the skin in close proximity to the wound. In this reconsideration, the specific evidence on electromagnetic therapy was considered. Taken together, the studies, while with various flaws, were consistent in the support of electromagnetic therapy for the treatment of chronic wounds. In general, the evidence on electrostimulation, whether direct or induced, is more substantial when considered together. In addition, the Diapulse Corporation provided plausible reasoning and evidence to consider electromagnetic therapy as one modality under electrostimulation for the treatment of chronic wounds.

Thus, there appears to be adequate evidence on the improvements in net health outcomes of electromagnetic therapy for the treatment of chronic wounds under the supervision of appropriately trained health care professionals. In contrast, there is insufficient evidence as noted above on the improvements in net health outcomes from unsupervised electromagnetic therapy for the treatment of chronic wounds provided by patients themselves in the home.

Therefore, it is our intention to modify CIM 35-102 to allow for coverage for the use of electrical and electromagnetic stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical and electromagnetic stimulation for the treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence, despite optimal treatment using standard wound care techniques.

Electrical stimulation and electromagnetic therapy for the treatment of wounds will not be covered as an initial treatment modality. The use of electrical and electromagnetic stimulation will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30-days of treatment with standard wound therapy and must be used in addition to standard wound care. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Specific wound care based on type of wound includes frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers; and the use of a compression system for patients with venous ulcers. Wounds must be evaluated at least every 30 days during administration of electrical and electromagnetic stimulation therapy. Continued treatment with electrical and electromagnetic stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Electrical and electromagnetic stimulation should be discontinued when the wound demonstrates a 100% epithelialzed wound bed. Electrical and electromagnetic stimulation for wound healing are not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary.

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1 Valk et al., 2001.

2 Ibid.

3 Cullum et al., 2001.

4 Low and Reed, 2000.

5 Stiller et al., 1992.

6 The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by the FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

7 In 2001, Cullum et al. conducted a technology assessment for the United Kingdom's National Health Service on the use of electrotherapy and electromagnetic therapy for the treatment of wounds.

8 Fleming K, Cullum N, 2002

9 www.cms.hhs.gov/coverage/default2.asp

10 Now known as the Agency for Healthcare Research and Quality.

11 Ieran et al., 1990.

12 Todd et al., 1991

13 Stiller et al., 1992

14 Salzberg et al., 1995.

15 Kenkre et al., 1996.

16 Druma-Drzewinska and Buczynski, 1978.

17 Itoh et al., 1991.

18 Tung et al., 1995.

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